

Glavi fU]XYbhZ] UWY'UXa]b]gfhUj b]]b'gd'cyb]]]b] b]]dcXUh_cj]nU'bfUj Yž
]b]gc'df]`f YbY'ghUbcžj]nXfUj ghj YbYa]j Ufghj i]fj]_`f bc'g'ghfc'bc'VYf`]j]a]
_UfhWUa]k

Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)

Struktur der Identifizierungs-, Verwaltungs- und der üblichen Medizindaten für im Gesundheitswesen angewandte intermittierend angeschlossene Geräte (einschließlich der maschinenlesbaren Karten) (standards.iteh.ai)

Structure des données d'identification, des données administratives et des données médicales communes pour les Dispositifs Connectés par Intermittance utilisés dans le domaine de la santé (y compris les cartes lisibles par machine)

Ta slovenski standard je istoveten z: ENV 12018:1997

ICS:

35.240.15	Identifikacijske kartice in sorodne naprave	Identification cards and related devices
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST ENV 12018:2003**en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST ENV 12018:2003

<https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003>

EUROPEAN PRESTANDARD
PRÉNORME EUROPÉENNE
EUROPÄISCHE VORNORM

ENV 12018

October 1997

ICS 11.020; 35.240.60

Descriptors: medicine, data processing, information interchange, data transmission, data, organization of data

English version

**Identification, administrative, and common clinical data structure
for Intermittently Connected Devices used in healthcare
(including machine readable cards)**

Structure des données d'identification, des données administratives et des données médicales communes pour les Dispositifs Connectés par Intermittence utilisés dans le domaine de la santé (y compris les cartes lisibles par machine)

Struktur der Identifizierungs-, Verwaltungs- und der üblichen Medizindaten für im Gesundheitswesen angewandte intermittierend angeschlossene Geräte (einschließlich der maschinenlesbaren Karten)

This European Prestandard (ENV) was approved by CEN on 30 October 1995 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents

Foreword	6
Introduction	7
1 Scope	9
2 Normative references	9
3 Definitions	11
4 Abbreviations	13
5 Basic data object model for an ICD	14
5.1 Object structure.....	14
5.2 Linking.....	14
6 Basic data objects for referencing	16
6.1 Overview.....	16
6.2 Generally useful types used for implicit definitions.....	16
6.2.1 Person name related data objects.....	16
6.2.1.1 The "Full Name" data object.....	16
6.2.1.2 The "Title" data object.....	16
6.2.1.3 The "Surname Prefix" data object.....	16
6.2.1.4 The "Surnames" data object.....	16
6.2.1.5 The "Surname" data object.....	16
6.2.1.6 The "Forenames" data object.....	16
6.2.1.7 The "Forename" data object.....	17
6.2.1.8 The "Name Element" data object.....	17
6.2.2 Address and telecommunication related data objects.....	17
6.2.2.1 The "Postal Address" data object.....	17
6.2.2.2 The "Post Code" data object.....	17
6.2.2.3 The "Country" data object.....	17
6.2.2.4 The "Date" data objects.....	17
6.2.2.5 The "Place" data object.....	17
6.2.2.6 The "Telecommunication" data object.....	17
6.2.2.7 The "Telephone Numbers" data object.....	18
6.2.2.8 The "X.400" and "Other Network Addresses" data objects.....	18
6.2.2.9 The "Money" data object.....	18
6.3 Basic data objects.....	18
6.3.1 Record persons.....	18
6.3.1.1 The "Record Persons" data object.....	18
6.3.1.2 The "Record Person" data object.....	19
6.3.1.3 The "Major Record Identifier" data object.....	19
6.3.1.4 The "Alternative Record Identifiers" data object.....	20
6.3.1.5 The "Record Identification Verification" data object.....	20
6.3.2 The "Device Specific Data" object.....	21
6.3.2.1 The "Device Type" data object.....	21
6.3.2.2 The "Device Class" data object.....	21
6.3.2.3 The "Device Standard" data object.....	21
6.3.2.4 The "Device Specifications" data object.....	21
6.3.2.5 The "Device Applications" data object.....	21
6.3.2.6 The "Device Specific Directory" data object.....	22
6.3.2.7 The "Device Identification" data object.....	22
6.3.3 Objects linking sites and persons.....	22
6.3.3.1 The "Healthcare Sites" data object.....	22



6.3.3.2	The "Healthcare Persons" data object.....	22
6.3.3.3	Linking of sites and healthcare persons : the "Site Mix Table" data object.....	23
6.3.4	Coded data	23
6.3.4.1	The "CodingSchemesUsed" data object	23
6.3.4.2	The "CodedData" data object.....	24
6.3.5	Attributes.....	24
6.3.5.1	Accessory attributes	24
6.3.5.2	Device and data security attributes.....	25
6.4	Link associations between objects	26
6.4.1	The "RecordPersonPointer" data object.....	26
6.4.2	The "ReferencePointer" and "ReferenceTag" data objects	26
6.4.3	The "Linkages" data object	27
6.5	Data from ICDs held by healthcare persons.....	27
7	Basic identification and administration data.....	27
7.1	The "Variable Identification Data" object.....	27
7.1.1	The "Address" data object.....	27
7.1.2	The "Record Person Telecom" data object.....	28
7.1.3	The "Preferred Languages" data object.....	28
7.1.4	The "Maiden Name" data object.....	28
7.1.5	The "Previous Surnames" data object.....	28
7.1.6	The "Other Names" data object.....	28
7.2	The "Record Person Post Code" data object	29
7.3	The "Record Person Country" data object	29
7.4	The "Contact Persons" data object	29
7.5	The "Record Person Visiting Instructions" data object.....	29
7.6	The "Payment Provisions" data object.....	30
7.7	The "Patient Payments" object	31
7.8	The "Other Coded Administrative Data" object.....	31
8	Clinical data.....	31
8.1	The "Clinical Coded Data" object	31
8.2	The "Parameter" data objects	32
8.2.1	The "Medication Note" parameter object.....	32
8.2.2	The "Medication Prescription" parameter object.....	32
8.2.3	The "Medication Administered" parameter object.....	33
8.2.4	The "Medication Dispensed" parameter object.....	33
8.2.5	The "Drug Sensitivity" parameter object	34
8.2.6	The "Laboratory Test Results" parameter object	34
8.2.7	The "Digital Binary Data" parameter object	34
8.2.8	The "Request" parameter object	34
8.2.9	The "Diagnosis" parameter object	34
8.2.10	The "Procedures" parameter object	35
8.3	The limited emergency data set	35
9	Specific ICDs security services related data objects.....	36
9.1	Patient devices security related data	36
9.2	Healthcare persons devices security related data.....	36
9.2.1	Healthcare persons access keys : the "PatientICDAccessData" data object.....	36
9.2.2	Healthcare persons authentication key : the "IdAuthenticateData" data object	37
9.2.3	Healthcare persons signature key : the "HCPSignFuncData" data object	37
9.2.4	Healthcare persons authentication and signature public keys and certificate	37
9.2.5	Object related security reference data.....	37
9.3	The "SecurityAttributes" data object	37

Annex A (informative) General points about ASN.1 data objects representation	38
A.1 ASN.1 definitions	38
A.2 ASN.1 syntax	39
A.3 The Tag-Length-Value format	39
A.4 The use of tags	40
A.5 Examples of using the Basic Encoding Rules for use with ASN.1 for objects in this standard	40
Annex B (normative) ASN.1 representation of data objects in this European Prestandard.....	42
B.1 Basic Data Objects for Referencing	42
B.1.1 Person Name related data objects	42
B.1.2 Address and Telecommunication related data objects	43
B.1.3 The "Money" data object	43
B.2 Basic Data Objects	43
B.2.1 The "Record Persons" data object	43
B.2.2 The "Major Record Identifier" data object	44
B.2.3 The "Alternative Record Identifiers" data object	44
B.2.4 The "Record Identification Verification" data object	45
B.3 The "Device Specific Data" object	45
B.3.1 The "Device Data" object	45
B.3.2 The "Device Type" data object	45
B.3.3 The "Device Applications" data object	45
B.3.4 The "Device Specific Directory" data object	46
B.3.5 The "Device Identification" data object	46
B.4 The "Healthcare Sites" data object	46
B.5 The "Healthcare Persons" data object	46
B.6 Linking of sites and healthcare persons : the "Site Mix Table" data object	47
B.7 Coded data and coding schemes	47
B.7.1 The "Coding Schemes Used" data object	47
B.7.2 The "Coded Data" data object	48
B.8 The "Accessory Attributes" data object	48
B.9 Link associations between objects	49
B.9.1 The "Record Person Pointer" data object	49
B.9.2 The "Reference Pointer" and "Reference Tag" data objects	49
B.9.3 The "Linkages" data object	49
B.10 Data from ICDs held by healthcare persons	50
B.11 Basic ID & Administration Data	50
B.11.1 The "Address" data object	50
B.11.2 The "Record Person Telecom" data object	50
B.11.3 The "Preferred Languages" data object	50
B.11.4 The "Maiden Name" data object	51
B.11.5 The "Previous Surnames" data object	51
B.11.6 The "Other Names" data object	51
B.12 The "Record Person Post Code" data object	51
B.13 The "Record Person Country" data object	51
B.14 The "Contact Persons" data object	52
B.15 The "Record Person Visiting Instructions" data object	52
B.16 The "Payment Provisions" data object	52
B.17 The "Patient Payments" data object	54
B.18 The "Other Coded Administrative Data" object	55
B.19 The "Clinical Coded Data" object	55
B.20 The "Parameter" data objects	56
B.20.1 The "Medication Note" parameter object	56

B.20.2	The "Medication Prescription" parameter object.....	56
B.20.3	The "Medication Administered" parameter Object.....	57
B.20.4	The "Medication Dispensed" parameter object.....	57
B.20.5	The "Drug Sensitivity" parameter object.....	58
B.20.6	The "Laboratory Test Results" parameter object.....	58
B.20.7	The "Digital Binary Data" parameter object.....	59
B.20.8	The "Request" parameter object.....	59
B.20.9	The "Diagnosis" parameter object.....	59
B.20.10	The "Procedure" parameter object.....	60
B.21	The Limited Emergency Data Set.....	60
B.22	Specific ICDs security services related data objects.....	61
B.22.1	Patient devices security related data.....	61
B.22.2	Healthcare persons devices security related data.....	62
Annex C (informative)	The hierarchy of data objects.....	64
C.1	Basic data objects for referencing.....	64
C.2	Basic data objects for identification and administrative purposes.....	67
C.3	Clinical data.....	70
C.4	Specific ICDs security services related data objects.....	72
Annex D (normative)	Application specific data object tags and their values.....	74
Annex E (informative)	Devices that may function as Intermittently Connected Devices.....	75
Annex F (informative)	Data Dictionary.....	77
F.1	Data types.....	77
F.2	Status of the attributes within the objects.....	78
Annex G (informative)	EDIFACT representation of a sample of data objects.....	99

SIST ENV 12018:2003

<https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003>

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Medical informatics", the secretariat of which is held by SIS.

This European Prestandard has been prepared under a mandate (BC-IT-217) given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST ENV 12018:2003

<https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003>

Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems ; therefore, during their operational lifetime they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems too. For instance prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible data bases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of intermittently connected devices for practical everyday healthcare delivery, the need has arisen for a standardised data format for interchange.

The data carried by an ICD can be categorised in three broad types: identification, administrative and clinical.

Identification data may include :

- identification of the device itself ;
- unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include :

- complementary person(s) related data ;
- identification of the funding of health care , whether public or private, and their relationships i.e. insurer(s), contract(s) and policy(ies) or types of benefits ;
- other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Common clinical data may include :

- items that provide information about health and health events ;
- their appraisal and labelling by a Healthcare Provider (HCP) ;
- related actions planned requested or performed ;
- the outcome of such actions (e.g. in terms of tests results).

Because there exists a need to optimise the use of memory by avoiding redundancies, and also because an ICD essentially provides specific answers to definite queries, "high level" Object Modelling Technique (OMT) has been applied with respect to ICDs data structure.

Data in the three categories above share many features. For instance, each may need to include ID numbers, names and dates. Some information may also have clinical as well as administrative uses. Therefore it has been considered inadequate to provide a simple list of items carried by ICDs without applying a generic organisation, based upon the existence of basic data elements. These may be defined by their characteristics (e.g. their format), and from them compound data objects may be constructed; several such objects may also share attributes.

This European Prestandard describes the data objects using plain text in normative clauses 6, 7, and 8.

Clause 6 defines basic data objects for referencing.

Clause 7 defines objects for :

- administrative data to allow identification of patient or of healthcare persons (professionals and other types of personnel) and of records belonging to them ;
- demographic and general administrative data.

Clause 8 defines objects for clinical data interchange requirements, with special emphasis on coded data.

Annex A gives general information about the ASN.1 syntax.

Annexes B, C, and D (normative) provide a representation of all objects using ASN.1 notation with the corresponding tags, whilst annex F provides a data dictionary, and annex G (informative) an EDIFACT representation of a sample of data objects.

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST ENV 12018:2003

<https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003>

1 Scope

This European Prestandard establishes a common framework for the content and the structure of identification, administrative and common clinical data. It applies exclusively to situations in which such data are recorded on or transported by Intermittently Connected Devices (ICDs) which are intended for use in healthcare.

This European Prestandard specifies the basic structure of the data, but does not specify particular data-sets for storage on devices.

To allow interoperability, whenever an application is built for use in the healthcare domain in compliance with this European Prestandard, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in clauses 6 to 8.

The detailed functions and mechanisms of the following services are not within the scope of this European Prestandard, (although its structures can accommodate suitable data objects elsewhere specified):

- security functions and related services which are likely to be recommended for ICDs depending on their specific application, for example: confidentiality protection, data integrity protection, and authentication of persons and devices ;
- access control services which may depend on active use of some ICD classes such as microprocessor cards ;
- the initialisation and issuing process (which begins the operating lifetime of an individual ICD, and by which the ICD is prepared for the data to be subsequently communicated to it according to this European Prestandard).

Data is extracted from an ICD in the form of a "message". This European Prestandard addresses the 'meaning' of the message within or at the interface between an ICD and an application system, not the 'method' of its origination or transmission.

<https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003>

The following topics are therefore beyond the scope of this European Prestandard :

- physical or logical solutions for the practical functioning of particular types of ICDs ;
- how the message is processed further 'downstream' of the interface between two systems ;
- the form which data takes for use outside the ICD, or the way in which such data is visibly represented on the ICD or elsewhere.

2 Normative references

This European Prestandard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

ENV 1068:1993

Medical informatics - healthcare information interchange - Registration of coding schemes.

EN 1387	Machine readable cards - Health care applications - Cards : General characteristics. ¹
EN 23166:1994	Codes for the representation of names of countries.
EN 27816-3:1992	Identification cards - Integrated circuit(s) cards with contacts - Part 3 : Electronic signals and transmission protocols.
EN 28601:1992	Data elements and interchange formats - Information interchange - Representation of dates and times.
ISO 639:1988	Codes for the representation of names of languages.
ISO 4217:1990	Codes for the representation of currencies and funds.
ISO 5218:1977	Information interchange - Representation of human sexes.
ISO 6093:1985	Information processing - Representation of numerical values in character strings for information interchange.
ISO 6523:1984	Data interchange - Structures for the identification of organisations.
ISO 7498-2:1989	Information processing systems - Open Systems Interconnection - Basic Reference Model - Part 2 : Security Architecture.
ISO/IEC 8824 : 1990	Information technology - Open Systems Interconnection - Specification of Abstract Syntax Notation One (ASN.1).
ISO/IEC 8825 : 1990	Information technology - Open Systems Interconnection - Specification of Basic Encoding Rules for Abstract Syntax Notation One (ASN.1).
ISO 8859-1 : 1987	Information processing - 8-bit single byte coded graphic character sets - Part 1 : Latin alphabet No.1.
ISO 8908 :1993	Banking and related financial services - Vocabulary and data elements.
ISO/IEC 9594-8 :1990	Information technology - Open Systems Interconnection : The Directory - Part 8 : Authentication framework.
ISO/IEC 9798-1 : 1991	Information technology - Security techniques - Entity authentication mechanisms - Part 1 : General model.
ISO/IEC 10181-2	Information technology - Open Systems Interconnection - Security Frameworks for Open Systems : Authentication Framework. ¹
CCITT	Numbering plan for the international telephone service.
Recommendation	
E.163	

¹ At present at the stage of draft.

¹ At present at the stage of draft.

3 Definitions

For the purposes of this European Prestandard, the following definitions apply.

3.1 alternative record identifier : An alternative record identifier is an identifier, composed of characters, that is not identical to the major record identifier and is related to the same record person.

3.2 asymmetric authentication method : Method for demonstrating knowledge of a secret, in which not all authentication information is shared by both entities.

3.3 confidentiality : The property that information is not made available or disclosed to unauthorised individuals, entities or processes. [ISO 7498-2 : 1989].

3.4 country : The code that identifies the country of origin of the device issuer.

NOTE : This may not necessarily be the same as the nationality of the device holder.

3.5 cryptographic key : Parameter used, in conjunction with an algorithm, for the purposes of validation, authentication, encipherment, or decipherment. [ISO 8908 : 1993].

3.6 cryptography : The discipline which embodies principles, means, and methods for the transformation of data in order to hide its information content, prevent its undetected modification and/or prevent its unauthorised use. [ISO 7498-2 : 1989].

3.7 data integrity : The property that data has not been altered or destroyed in an unauthorised manner [ISO 7498-2 : 1989].

3.8 data object : A data object is a collection of data that has a natural grouping and may be identified as a complete entity.

3.9 data origin authentication : The corroboration that the source of data received is as claimed [ISO 7498-2 : 1989].

3.10 data sub-object : A data sub-object is a component of a data object that itself may be identified as a discrete entity.

3.11 device holder : A device holder is an individual transporting an ICD which contains a record with themselves identified as the major record person.

3.12 digital signature : Data appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the data unit and protect against forgery e.g. by the recipient [ISO 7498-2 : 1989].

3.13 entity authentication : The corroboration that an entity is the one claimed [ISO/IEC 9798-1 : 1991].

3.14 erasure : The process whereby access to a data entity after a given point in time is permanently removed or access denied thereafter to all parties.

NOTE : This may not involve physical removal from the device, and may merely be the result of altering security such that access is permanently denied to all parties.

3.15 healthcare person device : An HCP device is designed to provide the function of allowing healthcare persons to have their identity and qualifications acknowledged by the information systems that they use, including informatics and telematics, and if necessary, to sign the transactions that they perform via these systems.

3.16 ICD application system : An application system that can communicate with an ICD.

3.17 ICD connecting unit : A physical device, which may also contain software elements, that enables communication to take place between an ICD and a host.

3.18 interface : May be both physical or electrical or logical. A hypothetical junction between an ICD and the external environment.

NOTE : This term can be used with a qualifier to describe an attribute to allow data flow to take place over this hypothetical point.

3.19 intermittently connected device (ICD) : An Intermittently Connected Device :

- a) stores person related information in computer readable format ; and
- b) supports data interchange ; and
- c) when used for data interchange does not require that the originator of the information receives 'confirmation of receipt' of the information".

NOTE : Many different types of hardware may be ICDs but it is important that being an ICD according to this definition is never an intrinsic aspect of the device itself but is dependant upon a certain usage. An ICD may have several uses and hardware functions other than the storage and transmission of person related data.

3.20 linkage : The ability to join together two or more entities or parts. It may be physical, electrical or relational.

3.21 major industry identifier (MII) : The code that identifies the sector/industry within which the ICD is intended for use.

3.22 major record identifier : The major record identifier is an identifier linked to a primary record relating to a record person within an ICD and a given healthcare delivery system.

3.23 personal identification number (PIN) : The PIN is a 4 to 12 character alphanumeric code or password the device holder possesses for the purposes of authentication.

3.24 record : A record is a collection of data.

3.25 record person : A record person is an individual about whom there is an identifiable record containing person related data.

3.26 security : The combination of confidentiality, integrity and availability.

3.27 soft network : A logical form of linkage in which message sender and recipient are not physically linked and in which message receipt confirmation may not be received by sender.

3.28 update : The process whereby information is erased and replaced by new information.

3.29 write : The process whereby information is added to the ICD.

4 Abbreviations

CAD	Card accepting device
HCP	Healthcare person
HCD	Healthcare coding scheme designator
ICC	Integrated circuit card
ICD	Intermittently Connected Device
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
PIN	Personal Identification Number
MII	Major Industry Identifier
UTC	Coordinated Universal Time

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST ENV 12018:2003](https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003)

<https://standards.iteh.ai/catalog/standards/sist/988172b5-e617-422a-9941-93537be2b166/sist-env-12018-2003>